



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,196	03/04/2002	Joseph P. Day	SP01-310 WJT003-0010	4725
22928	7590	08/01/2005	EXAMINER	
CORNING INCORPORATED			NOGUEROLA, ALEXANDER STEPHAN	
SP-TI-3-1			ART UNIT	
CORNING, NY 14831			PAPER NUMBER	

1753

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,196

Applicant(s)

DAY ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

18

DETAILED ACTION

Status of Rejections Pending since the Office action of April 13, 2005

1. All previous rejections are withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1753

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zare et al. (US 6,875,348 B2) ("Zare") in view of Powers ("the Development and Characterization of Sol Gel substrates for Chemical and Optical Applications, "Chapter 5 of Dissertation – 1998, University of Florida) ("Powers"). Note that although Zare (US 6,875,348 B2) was filed on April 16, 2002, after Applicants filing date of March 4, 2002, Zare has support back to August 13, 2001 through application No. 09/929,275, filed on August 13, 2001, now US 6,866,785 B2 (Zare*).

Addressing claim 41, Zare discloses a method for analyzing a biological sample, the method comprising the steps of

placing a silica sol gel monolith that has a plurality pores formed therein into an electrophoresis apparatus (Zare - col. 1:20-25; col. 3:30-37; col. 7:54-60; col. 8:39-63;

Art Unit: 1753

claim 2; col. 10:32-47; Figures 1A-1C; and col. 18:19-45 | Zare* - col. 2:15-25; col. 2:30-41; col. 5:48-54; col. 6:35-40; col. 7:20-33; claims 2, 4, and 8; col. 8:8-17; Figure 1A; and col. 14:29-56);

pouring a buffer into the electrophoresis apparatus to immerse the sol gel monolith (Zare - implied since the sol gel is inside a capillary that is filled with buffer; see Figures 1A-1C; col. 14:23-53; and col. 18:19-45 | Zare* - Figure 1A; and col. 8:8-17; and col. 14:29-56);

inserting the biological sample into the sol gel monolith (Zare - col. 6:16-27 and col. 18:19-45 | Zare* - col. 4:59-61; col. 14:7-56); and

applying power to the silica sol gel monolith such that molecules of the biological sample migrate within at least a portion of the plurality of pores formed within the sol gel monolith (Zare - col. 18:19-45 | Zare* - col. 14:7-56 and col. 8:8-14).

Zare does not mention an average diameter for the pores in the range of 30-400 angstroms. However, Zare clearly teaches controlling the pore size (Zare - col. 7:1-8; col. 8:25-29; col. 9:9-37; and col. 9:64-67 | Zare* - col. 5:65 to col. 6:24; and col. 6:58-62). Zare also alludes to a small pore since Zare discloses that the monolith can be formed in a capillary having an inner diameter of only 10 microns (Zare - col. 5:56-67 | Zare* - col. 4:18-28) and that it can be used to separate biomolecules such as DNA or proteins (Zare - col. 6:16-27 | Zare* - col. 4:59-61; col. 7:12-19 and col. 14:7-56).

Powers discloses a silica sol gel that may have pores in the range of 30-400 angstroms. Table 5.1 on page 146. Powers in fact considers the term "large pore" to

Art Unit: 1753

refer to any gel with a pore radius greater than 10 nm. See first paragraph on page 142.

Thus, barring a contrary showing, such as unexpected results, selecting the average pore size, such as in the range of 30-400 angstroms as taught by Powers, will depend on the sample, and was within the skill of one with ordinary skill in the art at the time of the invention, especially since Zare discloses controlling the pore size, having the monolith in a container with a very small diameter, and using the monolith to separate small biological molecules. Clearly, for example, the pores should not be smaller than the size of the analytes to be separated, but smaller than particles larger than the analytes of interest.

Addressing claim 43, it would have been obvious to one with ordinary skill in the art at the time of the invention to at least use the invention of Zare as modified by Powers to also analyze proteins because Zare discloses analyzing "charged species such as peptides." See Zare - col. 10:21-29 and Zare* - col. 7:12-19.

Addressing claim 44, this claim appears to introduce a product-by-process limitation that is unpatentable over Zare as modified by Powers unless a material

Art Unit: 1753

difference can be shown between the silica sol gel of Zare and that claimed by Applicants, especial since the silica sol gel of Zare comprises silicate (Zare - col. 8:3-5 | Zare* - col. 4:65 – col.5:3) and Zare discloses hydrolysis (Zare – col. 8:64 – col. 9:20 | Zare* - col. 5:55 – col. 6:8).

5. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zare et al. (US 6,875,348 B2) ("Zare") in view of Powers ('the Development and Characterization of Sol Gel substrates for Chemical and Optical Applications, "Chapter 5 of Dissertation – 1998, University of Florida) ("Powers"). as applied to claims 41, 43, and 44 above, and further in view of MacDonell ("Porous Glass Electrophoresis," *Analytical Chemistry*, vol. 33, no. 11, October 1961, pp. 154-1555) ("MacDonell") and Anazawa et al. (US 5,938,908) ("Anazawa").

Zare as modified by Powers does not disclose staining the biological sample and photographing the sol gel monolith. However, staining the sample and photographing the migrated molecules was a known detection technique at the time of the invention See Figure 2 of MacDonell. Anazawa discloses fluorescently labeling analytes and monitoring them with a camera. See col. 8:10-20. Barring a contrary showing, the choice of electrophoresis detection technique from known detection techniques will depend on factors such as the amount of information required, such as measure of concentration or just identification; degree of resolution, such as nucleic acid base sequencing; and selectivity of available stains. Using stains and photography is a

Art Unit: 1753

simple, inexpensive technique for recognizing separated analytes of interest compared with using a complicated optical laser detection system that requires chemical labeling of the sample components.

Final Rejection

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

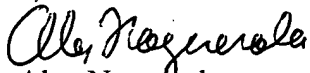
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1753

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
July 28, 2005